HFI-35 897



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Cincinnati District

Food & Drug Administration 1141 Central Parkway Cincinnati, OH 45202-1097

August 13, 1997

WARNING LETTER CIN-WL-97-540

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard G. Hillson, President Hillson Nut Company, Inc. 3225 W. 71st Street Cleveland, Ohio 44102

Dear Mr. Hillson:

During a Food and Drug Administration (FDA) inspection on July 23-24, 1997 of your food manufacturing facility located at the above address, our investigator collected samples of labels of shelled roasted Spanish peanuts manufactured and distributed by your firm. Our review of the labels revealed that they cause the product to be in violation of section 403 of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, <u>Code of Federal Regulations</u> (CFR), Part 101-Food Labeling.

The labels for your shelled roasted Spanish peanuts are misbranded within the meaning of section 403(q)(1) of the Act in that the labels fail to bear nutrition labeling as required under 21 CFR § 101.9 and they are not exempt under section 403(q)(5) of the Act from this requirement. The product bears a label statement "No Salt" which subjects it to the nutrition labeling requirements.

The above violation concerns certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statues enforced by FDA.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you have taken to correct the violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time period within which corrections will be completed.

Your reply to this letter should be sent to the Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,

Diana Kolaitis

Acting District Director Cincinnati District